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Amendments in Functional Foods Regulation Invite WTO Member Comments

Report Categories:

Sanitary/Phytosanitary/Food Safety
Exporter Guide
Food and Agricultural Import Regulations and Standards - Narrative

Approved By:
Mark Wallace
Prepared By:
Radha Mani

Report Highlights:

India has invited the World Trade Organization (WTO) members to provide comments on their amendments related to health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food. The comment period for trading partners expires 60 days beyond the notification date listed on the WTO website www.wto.org.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standard Authority of India's (FSSAI) website http://www.fssai.gov.in/. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

On January 9, 2018, FSSAI published amendments related to health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food. The notification invites comments from the WTO member countries, which would expire 60 days from the date it is published on the WTO website (www.wto.org). The said notification totals 45 pages and is available on the website of FSSAI at www.fsssai.gov.in.

Comments, within 60 days from the date of notification in the WTO website, should be sent to:

The Chief Executive Officer
Food Safety and Standards Authority of India
3rd Floor, Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: spstbt.enqpt@fssai.gov.in

Details of Notification:

- Date of Publication on FSSAI website: January 9, 2018
- Final date for comments from WTO members: 60 days from the date notified on WTO website

The compliance date for the standards related to foods mentioned above started as per the scheduled date of January 1, 2018. However, prior to this date, FSSAI published a directive on December 29, 2017 for all food business operators (FBOs) and provided certain exceptions relating to compliance timelines for these regulations which are listed below.

1. New ingredients and additives approved by the Scientific Panel as per Annexure I of the Regulation will be allowed to continue and used in their existing formulations until June 30, 2018. Wherever new and revised permissible limits are specified, FBOs will have a timeline until June 30, 2018 to reformulate their products. In case additional revisions take place in the list of ingredients or additives after June 30, 2018, then the FBOs will be granted a timeline of six months from the date of specifying new or revised limits to reformulate their products.
2. In case the ingredients have not been approved by the scientific panel due to inadequate data, the FBOs are given a timeline of four weeks from the date of issue of this directive, which was December 29, 2017, to submit data required by the Panel. However, they are allowed to continue businesses of their existing food products containing ingredients as per Annexure II of the Regulation until further orders from FSSAI. In case the FBOs fail to submit data within four weeks from the date of issuance of the directive, their products will be withdrawn from the market.
3. Because food products that include 'fluoride' and 'potato protein isolate' as ingredients are not

approved by the Panel due to safety concerns, the FBOs dealing with the businesses of such products have been directed to withdraw these products from the market discontinue their sale.

4. Products having 'willow bark extract', 'pyrrol quinolone quinone', and 'lemon bam' as ingredients have been identified by the Panel as exhibiting properties of drugs. FBOs doing businesses for such products are advised to discontinue; however, products already manufactured or imported are allowed to be sold until June 30, 2018.
5. FBOs are allowed to continue sales of existing products containing mere combinations of vitamins and minerals only up to one recommended daily allowance (RDA) in dosage formats such as tablets, capsules and syrups for the period of six months or until further notice, whichever is earlier.
6. FBOs are allowed to continue their existing formulations containing vitamins and minerals in Food for Special Dietary Uses without referring to the energy value (Kcal/KJ) as specified under Schedule III for a period of six months or until further notice, whichever is earlier.

For readers' convenience, the December 29th FSSAI Directive is pasted below at the end of this report and is available on FSSAI's website at: http://www.fssai.gov.in/home/fss-legislation/Advisories---Orders.html. All other background material on the subject Regulation can be referred from GAIN IN6145.

F. No. Stds/Nutra(DCGI)/ FSSAI/2017 (Pt 1)
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 29th December, 2017

Subject: Implementation of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

1. The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 has been notified by FSSAI on 23.12.2016. As per the notification, the Food Business Operators (FBOs) are required to ensure compliance of their existing and new products with all provisions of these regulations by 1st January, 2018.

2. Several representations have been received from stakeholders to include other ingredients and additives in these regulations since several ingredients/products containing these ingredients are already in the market based on the criteria given in para 3 of the directions issued vide ZF. No. 1-5/Nutraceuticals/FSSAI-2003 dated 6th January, 2017.

3. Scientific Panel met several times to discuss this issue and after careful consideration recommended the inclusion of some new ingredients in the regulations. However, some ingredients have not been approved to be included in the regulations due to safety issues or because they are likely to exhibit properties of drugs or because of inadequate data.

4. Since some of these issues are still under consideration of the Authority and finalization of the amendment to these regulations is likely to take some more time, the following timelines are laid down with respect to compliance to these regulations to ensure smoother transition for food businesses:

5. Ingredients and additives:

(i) Ingredients and additives approved by the Scientific Panel for inclusion: New ingredients and additives approved by the Scientific Panel and now included in the existing Schedules as per **Annexure I** are allowed to continue to

be used in the existing formulations. Where new/revised permissible limits of ingredients/additives have been specified, FBOs are given time till 30thJune, 2018to reformulate their products. In case new/revised permissible limits of ingredients/additivesare prescribed later, FBOs are given time for the period of six months from the date of specifying new/revised limits to reformulate their products.

(ii) Ingredients not approved by the Panel for inclusion due to inadequate data: FBOs are given time of four weeks from the date of issuance of this direction to submit data required by the Scientific Panel. Meanwhile, they are allowed to continue the food business of existing products containing ingredients as per **Annexure II** till further orders. Products containing these ingredients for which data is not submitted within four weeks from the date of issuance of this direction are to be immediately withdrawn from the market by the FBOs.

(iii) Ingredients not approved by the Panel for inclusion due to safety concerns: FBOs are directed to discontinue the food business of products carrying ingredients namely 'Fluoride' and 'Potato protein isolate' with immediate effect and withdraw the same from market.

(iv) Ingredients not approved by the Panel for inclusion since they exhibit properties of a drug: FBOs are directed to discontinue the food business of products carrying ingredients namely 'Willow Bark Extract', 'Pyrrol Quinoline Quinone' and 'Lemon Bam' which have been identified to exhibit properties of a drug with immediate effect. However, products already manufactured/ imported are allowed to be sold till 30th June 2018.

6. Restriction on mere combination of vitamin and minerals: FBOs are allowed to continue the food business of existing products containing mere combinations of vitamins and minerals only up to one RDA in dosage formats such as tablets, capsules and syrups for the period of six months or till further orders, whichever is earlier.

7. Schedule III with respect to FSDU category: FBOs are allowed to continue their existing formulations containing vitamins and minerals in Food for special dietary uses without referring to the energy value (Kcal/KJ) as specified under Schedule III for the period of six months or till further orders, whichever is earlier.

8. This issues with the approval of the Competent Authority in exercise of the power vested under Section 16 (5) of Food Safety and Standards Act, 2006.

Encls.: as above

(Sunil Bakshi)
Advisor (Regulations)

To

1. All Commissioners of Food Safety of All States/UTs.
2. All Authorised Officers, FSSAI.
3. All Central Designated officers, FSSAI.

Copy for information:

1. PPS to Chairperson, FSSAI.
2. PS to CEO, FSSAI.
3. All Divisional Heads in FSSAI, New Delhi.